



Association of
Metropolitan
Sewerage Agencies

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May 31, 2002

Docket ID No. OEI-10014
U.S. Environmental Protection Agency
Northeast Mall
Room B607
401 M Street, SW
Washington, DC 20460

Re: *Notice of Availability of Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, 67 Fed. Reg. 21234 (April 30, 2002)*

Dear Sir or Madam:

The Association of Metropolitan Sewerage Agencies (AMSA) is pleased to provide comments on the U.S. Environmental Protection Agency's (EPA's) *Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (Guidelines)*. Founded in 1970, AMSA represents the interests of over 270 of the nation's publicly owned wastewater utilities (POTWs). AMSA members serve the majority of the sewered population in the United States and collectively treat and reclaim over 18 billion gallons of wastewater every day. AMSA's members have an expressed interest in the quality of information disseminated by the Agency. POTWs are directly impacted by EPA's regulatory decisions as permittees under EPA's National Pollutant Discharge Elimination System (NPDES) and through other regulatory programs such as the 40 CFR Part 503 regulations for biosolids. Ensuring that these decisions are based on high-quality information is one of AMSA's top priorities.

Accordingly, AMSA continues to participate in numerous dialogues at the national level that focus on these key information quality issues. Most notably, we continue to advocate for Agency decisions based on high-quality, validated information regarding for example, whole effluent toxicity (WET) test methods, effluent guidelines, and total maximum daily loads (TMDLs).

AMSA applauds the efforts of the Office of Management and Budget (OMB) and EPA to ensure and maximize the quality, objectivity, utility, and integrity of information disseminated by the federal government and specifically EPA. AMSA firmly believes that these additional guidelines are needed. A number of recent EPA regulatory actions, including the recent approval of test methods for WET, suffer from a lack of transparency and have the appearance of being driven by policy or agenda as opposed to high-quality information and analysis. In the case of the WET methods, an added level of objective review and stricter adherence to established protocols would have dramatically increased stakeholder confidence in the Agency's actions.

AMSA hoped the *Guidelines* would provide more detail on EPA's specific actions to ensure the quality of information it disseminates. The current draft relies heavily on existing procedures, systems and manuals. While cross referencing existing standards avoids duplicative or contradictory policies and certainly reduces administrative burdens, it does not adequately address a number of critical issues. The current tools for ensuring the quality of information referenced in the *Guidelines* are not adequate. Additional procedures must be put in place to guarantee quality and objectivity. AMSA's specific comments on the *Guidelines* are outlined below.

Influential Information and Applicability of Guidelines

All Agency "information" should be considered influential. To some degree, every piece of information, whether it is data, opinion, policy or guidance, disseminated by the Agency has the potential to impact policy, private sector decisions, or public awareness. Such information is assumed to be accurate and of high quality as soon as it is released by the Agency. The public does not expect the Agency to release information that is not accurate or reliable. Furthermore, the public expects to get the all the facts relevant to a particular piece of information. Unfortunately, much information is currently released by the Agency without first being sufficiently reviewed. Imagine a report issued by the Agency that indicates that a potentially dangerous pollutant is present in most rivers and streams. Without the proper qualifying information, such as the fact that the pollutant was found at levels well below risk levels and that the Agency was unable to duplicate the results, the public perceives a health risk that simply does not exist. The information would better serve the public if it was properly qualified or further researched before dissemination.

The *Guidelines* as currently drafted are framed by a series of definitions. The first definition is that of "information." Information generally includes "any communication or representation of knowledge such as facts or data, in any medium or form." In defining information, EPA also defines what is not information, including internet hyperlinks, opinions, and other information at EPA's discretion. AMSA is concerned that the Agency will apply the *Guidelines* only to information that supports EPA's "viewpoint," or an Agency regulation, guidance, or other decision or position (lines 429-442). To withhold quality review until the Agency decides to use the information in a rulemaking or other action is inappropriate. The Agency must apply the *Guidelines* to any information that it uses.

The Agency further qualifies what is covered by the *Guidelines* by clarifying what "dissemination" means. EPA has excluded a number of actions from the definition of dissemination that AMSA believes should be subject to the *Guidelines*. For example, data released to EPA contractors (line 458) should

undergo quality checks to ensure that the work product EPA receives back from the contractor meets the established contract standards. It is counterproductive to employ a contractor and then provide them with less than accurate information. In addition, a request for records under the Freedom of Information Act (FOIA) implies that the requestor seeks true and accurate information. AMSA believes that information requested from the Agency in this manner should be held to these *Guidelines*. To release information to individuals (line 474-481) such as members of Congress without reviewing its quality is also inappropriate. Such actions could lead to legislation based on unsound science or facts. The release of information by EPA implies that the information has been reviewed for accuracy and quality and therefore such information must be subject to the *Guidelines*.

Reproducibility and Ensuring Information Quality

EPA does not adequately address the reproducibility standard in the *Guidelines*. AMSA encourages the Agency to specifically address the reproducibility of laboratory data. Reproducibility, as it applies to laboratory data or analytic results, means that an independent analysis of the original data using identical methods should generate similar analytic results, subject to an acceptable degree of imprecision or error. Accordingly, AMSA encourages the Agency to insist that test methods be validated using an interlaboratory study. Without such validation, the Agency would be unable to reliably predict the variability (or degree of imprecision) that would be encountered in testing a sample in different labs. In addition, test methods used for producing data should have adequate and mandatory QA/QC requirements to ensure that once a test method has been properly validated, that the labs conducting the test will run the method properly. EPA also must insist that any test method used be an approved method that has had an opportunity to be reviewed by the public.

EPA must require that supporting documentation accompany any information that is used and/or disseminated to ensure its reliability and reproducibility. For example, data below respective quantitation levels must be qualified accordingly. The *Draft Data Standard for Reporting Water Quality Results for Chemical and Microbiological Analytes*, recently released by EPA in the *Federal Register* (67 *Fed. Reg.* 34448) for comment, would be a good starting point. Characterizations of uncertainty also must be required for all information disseminated or used by the Agency.

EPA asked for suggestions on how to perform and report robustness checks of influential information where public access is limited. AMSA believes that robustness checks need to use tangible, quantifiable benchmarks that can be used for assessing all types of information. EPA must follow its own guidance (*Guidance for the Data Quality Objectives Process* and *Guidance on Data Quality Indicators*) and establish measurement quality objectives (MQOs) that are used for comparison when assessing whether the quality of information in question is acceptable. These MQOs must be established up-front and prior to initiation of the information review process to ensure objectivity. Use of such benchmarks is the only way to determine whether the *Guidelines* have been met, and whether the conclusions of an information review are reproducible. EPA's "graded" approach is too ambiguous for implementation and will only result in a lack of reproducibility between information reviews.

As with any process, EPA must have documented procedures for ensuring that the *Guidelines* have been met and that information that is disseminated is of high quality and integrity. As currently written, the

Guidelines are vague, rely heavily on inadequate existing procedures, and lack clear benchmarks for determining whether the *Guidelines* have actually been met. EPA must establish standards by which it will accurately and precisely determine whether information used and/or disseminated meets the desired level of quality.

Peer review, a tool currently used by EPA to ensure quality, is not itself a guarantee that the final product released by EPA or the original author meets the quality standard. In the case of the WET inter-laboratory study reported last year, EPA ignored many of the comments made by peer reviewers when the Agency issued its WET proposal in September 2001. A peer review can not ensure quality if the peer reviewer's comments are not incorporated or at least considered.

Influential Risk Assessment

AMSA supports the concept of assessing and communicating uncertainty regarding scientific risk assessment information. AMSA generally supports the quality principles as outlined in the *Guidelines* and suggests applying the same principles used for human health risk assessments to environmental and safety risk assessment information.

Sources of Information

EPA must accept ownership of information generated outside the Agency once it decides to use the information. Such information must be held to the same standards as information generated within the Agency. For example, EPA's Permit Compliance System (PCS) uses data from state regulatory agencies. In one instance, the Hampton Roads Sanitation District (HRSD) in Virginia was placed on EPA's Significant Noncompliance Report (SNR) for two consecutive years despite having perfect permit compliance. Investigation into this situation resulted in a claim by both the state and federal agencies that the other was at fault and therefore responsible for correcting the data. The state claimed that it sent the correct information and that the information was modified during transfer to the EPA database format. EPA stated that since the state sent the information, EPA had to assume it was ready for use.

Incorrect or inadequately qualified information can lead to unfounded concern. In the example above, an environmental research group published a report based on the EPA PCS information and cited a HRSD discharge as a risk to the public since the facility was "listed" on the SNR. When HRSD contacted the environmental research group to inform them that the conclusions of the report were based on incorrect data and therefore in error, HRSD was informed that the research group had no intention of printing a corrected version of the report. The research group's position was that EPA had provided the information and ensured the group that the information was correct, and therefore, the group had no further obligation to pursue the matter. EPA must not only check the accuracy of the information it receives, but also commit to a quality review of all information before releasing it to the public.

EPA states in Section 2.3 (lines 61-62) that it is committed to expanding "the public's right to know and understand their environment by providing and facilitating access to a wealth of information about local environmental issues and conditions." AMSA supports the public's right to know and believes that EPA must ensure information disseminated to the public is true and accurate, just as NPDES permittees are required to do when providing Discharge Monitoring Reports to regulatory agencies. Regulatory

agencies demand data certification from permittees and these agencies must hold themselves to the same standard when disseminating information to the public.

Complaint Resolution

AMSA recommends that EPA stipulate a 30-day time limit for complaint resolution. AMSA also recommends that the information in question be removed from public access until the resolution process has been completed. The public assumes that released information is accurate and is unlikely to follow-up in the future to determine if any changes have been made. Therefore, removal of the information in question until the dispute is resolved is the only way to ensure the information will not be misused or misinterpreted.

In order to streamline the resolution process, EPA should list a point of contact specific to each piece of information or information source (e.g., publication or database). This will minimize the amount of time spent attempting to determine the source of the information. The Agency must investigate and resolve any dispute regarding disseminated information promptly to ensure that only quality information is available to the public. As it does not take an executive panel or a top EPA official's authorization to release information to the public, it should not take their authority to correct inaccurate information. The highest level official involved in the publication of the information should be authorized to change the information if it is determined not to meet the *Guidelines*. If that official refuses to make the correction, then an executive review panel must make the final decision.

AMSA encourages the Agency not to exclude from consideration any request for correction made in reference to EPA actions where a mechanism for submitting comments to the Agency is already provided. This would include any information that is part of an Agency rulemaking or activity where public comments are requested. Oftentimes the length of the public comment period and the interim between the beginning of the public comment period and the next Agency action is quite long, and there should be procedures to correct inaccurate information separate from the rulemaking process. If this information is to be held to the same quality standards as is indicated in the *Guidelines*, it must be subject to the same mechanisms for reviewing its accuracy.

EPA states in the *Guidelines* that it "may elect not to correct some completed information products on a case-by-case basis due to Agency priorities, time constraints, or resources." AMSA believes this type of discretionary control is not appropriate and that all errors must be corrected by the Agency once confirmed.

EPA's Next Steps

AMSA is concerned that the Agency will make critical decisions about the reproducibility issue and other components of the *Guidelines* following the current comment period and finalize the *Guidelines* absent another public comment opportunity. The Agency has acknowledged that a number of the contentious issues, such as reproducibility, were not resolved prior to the release of this draft, and AMSA firmly believes that another round of review is appropriate. Accordingly, AMSA encourages the Agency to provide another draft of the *Guidelines* for review once these key policy decisions have been made.

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Thank you again for the opportunity to comment on this critical effort. AMSA looks forward to continued discussions with the Agency on this matter. If you have any questions about our comments please do not hesitate to call me at 202/833-9106.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Hornback". The signature is fluid and cursive, with a large initial "C" and "H".

Chris Hornback
Director, Regulatory Affairs